SUPPORT FOR THE AMENDMENTS

Applicants have amended Claim 1 to change "preventing and/or treating" to "treating." Support for this amendment can be found in Claim 1, as originally filed. Claim 1 has also been amended to recite the presence of "a nitric oxide-releasing agent selected from the group consisting of glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, molsidomine, and S-nitroso-N-acetyl-DL-penicillamine." Support for this amendment can be found on page 13, of the specification. Claims 2-6 have been amended to properly depend from amended Claim 1 and for clarity. Accordingly, support for amended Claims 2-6 can be found in the same claims, as originally filed.

Applicants have also added new Claims 7-20. Support for new Claims 7-20 can be found in Claims 1-6, as originally filed.

No new matter has been added. Claims 1-20 are active in this application.

REMARKS/ARGUMENTS

Present Claims 1-6 relate to compositions for treating the expression of clinical symptoms in a disease caused by mitochondrial dysfunction, wherein said composition is an orally administrable composition comprising L-arginine as an active ingredient and a nitric oxide-releasing agent selected from the group consisting of glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, molsidomine, and S-nitroso-N-acetyl-DL-penicillamine.

Present Claims 7-13 relate to methods for treating the expression of clinical symptoms in a disease caused by mitochondrial dysfunction, comprising orally administering to a subject in need thereof a composition comprising L-arginine as an active ingredient.

Present Claims 14-20 relate to methods for treating a disease caused by mitochondrial dysfunction, comprising orally administering to a subject in need thereof a composition comprising L-arginine as an active ingredient.

The present inventors have found that the presently claimed compositions and methods are particularly effective for treating the expression of clinical symptoms in a disease caused by mitochondrial dysfunction and for treating a disease caused by mitochondrial dysfunction. The cited reference contains no disclosure or suggestion of the presently claimed compositions or methods. Accordingly, this reference cannot affect the patentability of the present claims.

The rejection of Claims 1-4 under 35 U.S.C. § 102(b) in view of U.S. Patent No. 5,891,459 (Cooke et al.) is respectfully traversed. Simply put, Cooke et al. does not disclose or suggest any compositions which contain a nitric oxide-releasing agent selected from the group consisting of glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, molsidomine, and S-nitroso-N-acetyl-DL-penicillamine.

In sharp contrast, as noted above, Claim 1 has been amended to recite the presence of just such an agent. For this reason, Cooke et al. can neither anticipate no make obvious Claim 1 or the claims dependent thereon.

As for new Claims 7-20, Cooke et al. does not disclose or suggest any method for treating either the expression of clinical symptoms in a disease caused by mitochondrial dysfunction or a disease caused by mitochondrial dysfunction. Accordingly, Claims 7-12 are also patentable over this reference.

For these reasons, the rejection should be withdrawn.

The rejection of Claims 1-4 under 35 U.S.C. § 112, first paragraph, for lack of enablement, has been obviated by appropriate amendment. As the Examiner will note, the claims have been amended to delete "preventing." Accordingly, the rejection is no longer tenable and should be withdrawn.

The rejection of Claims 1-4 under 35 U.S.C. § 112, first paragraph, for lack of written description, is respectfully traversed. On page 8 of the Office Action, the position is taken

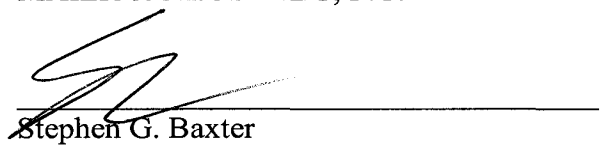
that the specification does not adequately describe what is meant by the term "clinical symptoms in a disease caused by mitochondrial dysfunction" and "warning symptom thereof." However, Applicants direct the Examiner's attention to pages 1-6 of the present specification where these terms are described in detail. Thus, the rejection is improper and should be withdrawn.

The objection to Claims 5 and 6 under 37 C.F.R. § 1.75(c) has been obviated by appropriate amendment. As the Examiner will note, the claims have been amended to remove all multiple dependencies. Accordingly, the objection should be withdrawn.

Applicants submit that the present application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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